1. PURPOSE

1.1. This procedure establishes the process when the Rutgers University IRB agrees to rely on an External IRB for review (i.e. cede review).

1.2. The process begins when the Principal Investigator submits an application in eIRB+ requesting the use of an External IRB.

1.3. The process ends when the IRB Authorization Agreement is no longer needed because the project is closed or one of the parties has withdrawn from the agreement.

2. PREVIOUS VERSION

2.1. 7/1/2020

3. POLICY

3.1. In accordance with 1.001 (HRP-101) - Human Research Protection Program Plan, the Rutgers University HRPP/IRB Office:

3.1.1 Reviews and determines if it is appropriate to execute an Authorization Agreement for the Rutgers University IRB to cede IRB review to (i.e. rely on) an External IRB.

3.1.2 Performs routine post-approval monitoring activities or conducts directed (for cause) reviews of study records. These oversight activities may be accomplished remotely, in collaboration with the external institution's IRB/Compliance team located at the participating research site.

3.2 The use of an External IRB may be warranted when one or more of the following are applicable:

3.2.1 Rutgers University is a sub-contracted site and IRB approval for the overall study has been provided by the external institution/organization.

3.2.2 The request is mandated by the funding agency per Single IRB or Cooperative Research requirements.

3.2.3 The request is mandated by the study sponsor or funding agency in order for the Rutgers University site to participate in the research.

3.2.4 The Rutgers University site is collaborating with the main research site for the study and receiving of identifiable information.

4. RESPONSIBILITIES

4.1. Rutgers University Principal Investigator:

4.1.1. Complies with all submission and reporting requirements of the External IRB.

4.1.2. Follows procedures below to submit a new study application to Rutgers University's IRB (via the eIRB+ system), including the relevant study information and Local Context Supplement in order for the IRB Office staff to make an initial assessment, and submits subsequent External IRB study updates/renewals to Rutgers University's IRB, as applicable.

4.1.3. Obtains all appropriate institution/organization approvals (i.e. IRB, IBC, ORSP, COI, etc.), prior to implementation of procedures at Rutgers University.

4.1.4. Complies with applicable local New Jersey laws, regulations, and Rutgers University policies, such as the 1.001 (HRP-101) - Human Research Protection Program Plan and 1.002 (HRP-103) - Investigator Manual.

4.1.5. Ensures that all collaborators and study staff are appropriately qualified, have completed Human Subjects Protections training, and have been adequately trained to conduct the study in alignment with the IRB approved protocol.

4.1.6. Promptly reports any Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs), termination or suspension of the study to Rutgers University's IRB

(For reporting requirements and timeframes, please consult the IRB Office's Reportable Events website

4.1.7 Maintains documentation of External IRB approval and other study documentation in accordance with 1.002 (HRP-103) Investigator Manual/1.005 (HRP-103p) pSite Investigator Manual.

5. PROCEDURE

5.1. The Principal Investigator, IRB Administrator (IRBA), and Reliance Administrator (RA) conduct the following procedures:

5.1.1. Initial Review

5.1.1.1. The Principal Investigator submits a new study application in eIRB+ and includes the following documents in the submission:

5.1.1.1.1 The study protocol and approved consent form.

5.1.1.1.2 Local context supplement

5.1.1.1.3 Investigator's brochure (if applicable).

5.1.1.1.4 Institutional Authorization Agreement template with Rutgers University site information. The Authorization Agreement should be on the external IRB's letterhead. If the external IRB does not have their own template, 13.302 (HRP-890) FORM - Single Study Authorization Agreement should be used.

5.1.1.2. The IRBA reviews the new study application in eIRB+:

5.1.1.2.1. Conducts the preliminary administrative review (PAR) before re-assigning the application to the RA. Using the procedures outlined in 13.204 (HRP-1801) WORKSHEET: Authorization Agreement Review, the RA reviews the application and determines if the request to cede review is appropriate.

5.1.1.2.1.1. If appropriate, the RA follows the process outlined in, 13.007 (HRP-801) SOP - Establishing Authorization Agreements, and forwards the partially executed Authorization Agreement to the local Rutgers University research team to proceed with the external IRB's processes.

5.1.1.2.2. Ensures that the Rutgers University consent form includes the required local context language (which includes, but is not limited to, conflict of interest, research costs, research injury and HIPAA language).

5.1.1.2.3. Ensures the eIRB+ new study the eIRB+ new study application contains all study documents approved by the External IRB.

5.1.1.2.4. Finalizes and issues in eIRB+, 3.312 - LETTER: Notice of Acknowledgement for Initial Administrative Review.

5.1.2. Continuing Review and Modifications

5.1.2.1. The Principal Investigator is required to submit the External IRB approval letters to Rutgers University via eIRB+, for study updates/renewals of the External IRB approved research that meet the following criteria:

5.1.2.1.1. Updates to Principal or co-Investigators.

5.1.2.1.2. Updates to protocol or consent forms.

5.1.2.1.3. External IRB Continuing review approval of the Rutgers study site.

5.1.2.1.4. In the event that the Principal Investigator has failed to renew the study with the External IRB by the expiration date, the Principal Investigator must notify the Rutgers University IRB in writing within 24 hours of study expiration.

5.1.2.2. The IRBA conducts the PAR then re-assigns the application to the RA.

5.1.2.2.1. Verifies all applicable local context information is included.

5.1.2.2.2. Finalizes and issues in eIRB+, 3.316 - LETTER: Notice of Modification Administrative Review.

5.1.3. Reportable New Information

5.1.3.1. Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs) that -involve Rutgers University or its affiliates' study participants are not required to be submitted to the Rutgers University IRB, unless the UP(s) is a death related to the research, a protocol deviation, or results in serious or continuing non-compliance.

5.1.4. Study Termination

5.1.4.1. The Rutgers IRB Office considers study closure a change in status. Therefore, the Principal Investigator is required to submit the External IRB closure documentation to the Rutgers University IRB.

5.1.4.1.1. The CAS or IRBA finalizes and issues in eIRB+, 3.315 - LETTER: Notice of Final Report Approval.

6. MATERIALS

6.1. 1.001 (HRP-101) - SOP - Human Research Protection Program Plan.
6.2. 1.002 (HRP-103) - SOP - Investigator Manual.
6.3. 1.004 (HRP-103p) – SOP - pSite Investigator Manual.
6.4. 3.006 (HRP-055) – SOP – Financial Conflicts of Interest.
6.5. 3.312 – LETTER - Notice of Acknowledgement for Initial Administrative Review (Automatically generated by eIRB+).
6.6. 3.315 - LETTER – Notice of Final Report Approval (*Automatically generated by eIRB+*).
6.7. 3.316 – LETTER – Notice of Modification Administrative Review (*Automatically generated by eIRB+*).
6.8. 13.007 (HRP-801) - SOP - Establishing Authorization Agreements.
6.9. 13.204 (HRP-1801) - WORKSHEET - Authorization Agreement Review.
6.10. 13.302 (HRP-890) - FORM - Single Study Authorization Agreement.

7. REFERENCES

7.1. NOT-OD-16-094: Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research.